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Health informatics — Requirements for an electronic health record architecture

Informatique de santé — Exigences relatives à une architecture de l'enregistrement électronique en matière de santé

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18308 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This first edition cancels and replaces ISO/TS 18308:2004, of which it constitutes a technical revision.

Introduction

Context

This International Standard defines the set of requirements that shall be met by the architecture of systems and services processing, managing and communicating electronic health record (EHR) information. This is in order to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes.

For the purposes of this International Standard, the EHR is defined as:

> "one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and healthcare of an individual, capable of being stored and communicated securely and of being accessible by multiple authorized users, represented according to a standardized or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated healthcare."

To complement this definition, the ideal vision of health (and consequently health information) is reflected in the WHO definition from 1946[1)]:

> "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

The scope of the EHR is recognized as being broader than the documentation of illnesses and their prevention and treatment. The systems and services that are deemed potential contributors to an EHR will increasingly include systems capturing complementary therapy, wellness, and home care information in addition to the conventional clinical systems within healthcare provider organizations.

The notion of the personal health record (PHR)[2)] is also maturing internationally and, while this International Standard does not specifically focus on the PHR, its requirements have been deliberately worded to be inclusive of the PHR in general terms, i.e. most of these EHR requirements will also apply to the PHR.

It is recognized, as a limitation, that no authoritative source of requirements has been found for the records of any of the complementary or traditional forms of healthcare practised internationally. Indeed, a recent literature review has suggested that there is a real lack of published work on the use of electronic health records within complementary healthcare or on the sharing of these health records (paper or electronic) with allopathic medicine[23]. It is equally the case that there is a lack of consensus requirements for systems to support wellness, social, and home care, but these systems will increasingly play an interactive role with EHRs, and information in them might become part of the EHR.

This International Standard is intended to be used when designing the architecture of health information services that incorporate or interact with electronic health record systems (EHR-Ss) or repositories.

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1) WHO. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946, and entered into force on 7 April 1948. Available from: http://www.who.int/governance/eb/who_constitution_en.pdf

2) The personal health record is generally taken to mean a health record whose content is primarily managed by an individual, while the EHR is generally taken to mean a health record that is controlled and managed by a healthcare provider (organization or person), but to which the subject of care normally has certain rights. It is recognized that a clear distinction does not always exist between these kinds of records.

EHR architectures

The requirements in this International Standard relate to shared EHR information [sometimes referred to as the “shared health record” (SHR), “shared care record” (SCR), or “health information exchange” (HIE)] and those aspects of governance within and between EHR systems that may be used to support and coordinate patient-centred continuity of care. The EHR for a subject of care might be scattered physically across multiple (discrete or interconnected) clinical systems and repositories, each of which will hold and manage a partial EHR for each of its subjects of care, scoped according to the service or community settings, clinical domains and time periods of use of that system in the life of each person.

The use of distributed computing mechanisms could permit a more holistic EHR to be realized, subject to relevant permissions. This holistic EHR will sometimes be stored and regularly updated in a centralized EHR repository (e.g. through a national e-health infrastructure), might be organized and accessed according to national indexing structures, or might only materialize just in time as a result of distributed querying across a distributed set of repositories. The formal (structural and functional) description of a system of components and services for recording, retrieving, and handling information in EHRs is known as an *EHR architecture*: this International Standard therefore defines the requirements for an EHR architecture (EHRA).

The Open Group Architecture Framework (TOGAF)[3] explains an architecture as:

> “a formal description of a system, organized in a way that supports reasoning about the structural properties of the system. It defines the system components or building blocks…and provides a plan from which products can be procured, and systems developed, that will work together to implement the overall system.”

This International Standard is not concerned with the specific requirements that individual (localized) applications and EHR repositories and services need to meet, but with the common set of requirements that ALL shall meet in order to permit their EHR data to be safely communicated and combined to form richer and more complete EHRs. It is therefore primarily concerned with the EHR from the perspective of a user or purchaser, and corresponds to the RM-ODP enterprise viewpoint perspective (reference model of Open Distributed Processing ISO/IEC 10746-1) rather than its technical specification.

It should be noted that the progressive adoption of electronic health records and systems globally will often be complemented by other changes to the business processes of healthcare and health services, some of which might be mediated through the functions and workflows of EHR systems, and other changes effected through training and the development of new staff roles and new healthcare resources. The business objectives defined in Clause 5 are likely to require a holistic approach to their realization rather than to arise as a direct result of the EHR in isolation.

EHR architecture and EHR system requirements

An EHR system will comprise one or more data repositories, directory services listing human and other resource entities, knowledge services containing terminological systems, care pathways and workflows, end user applications, reporting modules, security services, etc. The requirements for an EHR system relate closely to the functionality that end users will experience directly, and will reflect the business processes to be supported at the care setting in which the system is deployed. In contrast, an EHRA focuses on the infrastructure (the structure and functional relationships of components) managing the health information assets, which might include multiple EHR systems and repositories, and other systems that are beyond the scope of a single care setting (such as national registries of healthcare professionals). Inevitably, though, some requirements for EHR systems and EHR architectures will be common.

A separate and complementary International Standard, ISO/HL7 10781:2009, the HL7 EHR-S functional model, defines the requirements that shall be met by individual EHR systems. The authors of this International Standard and ISO/HL7 10781:2009 have reviewed both standards and verified that there are no conflicting requirements between them. It has not been possible to produce a detailed mapping of common themes, because the requirements statements are expressed at different levels of granularity between the two

3) See http://www.opengroup.org/togaf/ for more information.

International Standards. However, it is recognized that a more precise indication of overlap is a desirable future strategy for both International Standards, when they are next due for revision.

ISO has two complementary documents that specify the requirements of good practice for a clinical data warehouse: ISO/TR 22221 and ISO/TS 29585. These publications clarify good practice in information governance, the protection of privacy, the handling of metadata, management of data quality and general architectural principles. It is anticipated that many clinical data warehouses, used for health system quality monitoring, research and data mining, will be derived from EHR repositories, and many of the information provenance and governance requirements overlap. It is also possible for data flows to work in the opposite direction: for a clinical data warehouse to feed an EHR. There is growing interest internationally in exploring how best to unify these two functions within a single implemented repository; in this case, the requirements and principles for both an EHR architecture and a clinical data warehouse will need to be met.

Approach to defining these requirements

This International Standard updates and replaces ISO/TS 18308:2004, the first normative set of comprehensive requirements for an EHR architecture. Much has been learned since 2004, and several other complementary standards relating to the EHR have been published or are in development. Whereas ISO/TS 18308:2004 drew on and synthesized a significant body of requirements published by research and national projects, this International Standard has been able additionally to draw on a now more mature experience base in the design and use of EHR systems and early experience of large scale e-health infrastructures. Further, it has been possible to build on work done to develop other EHR quality and interoperability standards such as ISO 13606, HL7 v3 Clinical Document Architecture, HL7 v3 Care Provision Message for Record Exchange, the HL7 EHR System Functional Model, and the work of the *open*EHR Foundation. The inputs to this International Standard have therefore included expertise from many standards developers, as well as member bodies who now have experience using ISO/TS 18308:2004.

Requirements statements for computer systems and software should ideally comply with IEEE 830-1998, and should be verifiable, traceable, unambiguous, correct, and relevant. Many of the requirements in this International Standard, particularly those in the ethico-legal category, come under the SRS (software requirements specification) heading of constraints for which the IEEE specification is less precise. Nevertheless, this International Standard follows these IEEE principles as closely as possible.

Ideally each statement below should reference the original published sources of the requirement (as part of its traceability). However, the formal attribution of individual requirements to sources on this scale is neither practical nor faithful. In the 15 year period since some of the earliest publications used by this International Standard, there has been much cross-fertilization of ideas and cross-inclusion of requirements in newer publications, with some improvement and updating as the scope of electronic health records has evolved. Individual publications often cover similar requirement themes to a different level of granularity or stress different perspectives. Although many of the original source publications targeted the specific needs of a country, professional group or implementation scenario, the collated statements attempt to express these requirements in the most generic way possible. This International Standard therefore does not provide citations for the individual requirements statements. The bibliography lists the more substantive publications of generic EHR requirements that have been reviewed during the drafting of this International Standard and ISO/TS 18308:2004.

As for any International Standard and as per ISO/IEC Directives, Part 2, 2004, an EHRA conforms to this International Standard if it can demonstrate conformance to all of the mandatory requirements in Clause 6: those specified using the word “shall”. A small number of requirements in Clause 6 use the word “should”; these are not considered mandatory at the time of publication either because they are as yet too ambitious or might only be of importance in some care settings or countries. It is recognized that this demonstration of conformance will require the development of test plans that are derived from these requirements, and which may also need to reflect any additional local business requirements and anticipated context of use of the EHR architecture.

The EHR business objectives specified in Clause 5 are all optional, but are included as a perspective on the goals to which an EHR and its architecture should contribute, and which have informed the requirements of Clause 6.

Health informatics — Requirements for an electronic health record architecture

1 Scope

This International Standard defines the set of requirements for the architecture of a system that processes, manages and communicates electronic health record (EHR) information: an EHR architecture. The requirements are formulated to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice and facilitate data analysis for a multitude of purposes.

This International Standard does not specify the full set of requirements that need to be met by an EHR system for direct patient care or for other use cases, but the requirements defined by this International Standard do contribute to the governance of EHR information within such systems.

2 Notation

Each business objective statement in Clause 5 and each requirement statement in Clause 6 is prefixed by a short code. These codes are internal unique identifiers for the statements, to assist in referring to them in other resources such as test plans. These are non-semantic identifiers; they convey no specific meaning in themselves and do not serve to alter the interpretation of the statements they identify. They bear no relation to identifiers used in any other publication.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
architecture
system
structure of components, their functions, their inter-relationships, and the principles and guidelines governing their design and evolution over time

NOTE Adapted from the Open Group Architecture Framework (TOGAF), 2009.

Source: http://www.opengroup.org/architecture/togaf8-doc/arch/chap01.html#tag_02_03.

3.2
attestation
process of certifying and recording legal responsibility for a particular unit of information

[ISO 13606-1:2008, 3.8]

3.3
audit trail
chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed

[ISO 13606-1:2008, 3.9]

3.4
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

NOTE Adapted from ISO 7498-2:1989, 3.3.22 and 3.3.40.

3.5
authorization
granting permissions

NOTE Adapted from ISO/TS 22600-1:2006, 2.6.

3.6
availability
property of being accessible and useable upon demand by an authorized entity

[ISO 7498-2:1989, 3.3.11]

3.7
care plan
personalized statement of planned healthcare activities relating to one or more specified health issues

NOTE Adapted from EN 13940-1:2007.

3.8
clinical information
information about a person, relevant to his or her health or healthcare

[ISO 13606-1:2008, 3.13]

3.9
clinical process
set of interrelated or interacting healthcare activities performed by one or more healthcare professionals

3.10
code meaning
element within a coded set

[EN 1068:2005]

EXAMPLE “Paris Charles-De-Gaulle” which is mapped on to the three-letter abbreviation “CDG”” by the coding scheme for three-letter abbreviations of airport names.

3.11
code value
result of applying a coding scheme to a code meaning

[EN 1068:2005]

EXAMPLE “CDG” as the representation of “Paris Charles-De-Gaulle” in the coding scheme for three-letter representations of airport names.

3.12
coded set
set of elements that is mapped on to another set according to a code

[ISO/IEC 2382-4:1999, 04.02.02]

3.13
code
coding scheme
collection of rules that maps the elements of a first set on to the elements of a second set

[ISO/IEC 2382-4:1999, 04.02.01]

NOTE The two sets considered here are

— a set of “code meanings” (or “coded set”), and

— a set of “code values” (or “code set”).

Those sets are not *per se* part of the coding scheme.

3.14
coding system
combination of a set of code meanings and a set of code values, based on a coding scheme

[EN 1068:2005]

NOTE Code meanings are typically represented by terms or rubrics, but they can have other representations. Code values are typically numeric or alphanumeric.

3.15
concept
unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000, 3.2.1]

3.16
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[ISO 7498-2:1989, 3.3.16]

3.17
consent
agreement, approval, or permission as to some act or purpose given voluntarily by a competent person

[*Black's law dictionary*, 2009]

3.18
de-identification
process of removing the association between a set of identifying data and the data subject

[ISO/TS 25237:2008, 3.18]

3.19
directive
instruction how to proceed or act

[*Concise Oxford English dictionary*. Oxford: Oxford University Press, 2008]

3.20
electronic health record
EHR
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

3.21
electronic health record architecture
EHRA
formal description of a system of components and services for recording, retrieving and handling information in electronic health records

3.22
electronic health record system
EHR-S
system for recording, retrieving and manipulating information in electronic health records

[ISO 13606-1:2008, 3.26]

3.23
entity
concrete or abstract thing of interest, including associations among things

NOTE Adapted from ISO/IEC 2382-17:1999, 17.02.05.

3.24
entry
documentation of a discrete item of health information

NOTE An entry can, for example, represent the documentation of a clinical observation, an inference, an intention, a plan or an action.

3.25
explicit consent
agreement, approval or permission that is freely and directly given, expressed either *viva voce* or in writing or other legally authorized signature, e.g. electronic

3.26
healthcare
activities, services, or supplies related to the health of an individual

[EN 13940-1:2007]

3.27
healthcare activity
activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health of that subject of care

[EN 13940-1:2007]

3.28
health information
information about a person relevant to his or her health

3.29
health issue
issue related to the health of a subject of care, as identified or stated by a specific healthcare party

[EN 13940-1:2007]

3.30
healthcare party
organization or person involved in the process of healthcare

[EN 13940-1:2007]